DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HF-43

Food and Drug Administration
Rockville MD 20857

September 29, 1987

The Honorable Henry A. Waxman
Chairman, Subcommittee of Health
and the Environment
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Waxman:

This is in further response to your letter of July 1 concerning two nicotine-containing products, "IPCO Creamy Snuff" and "Masterpiece Tobacs." I would first like to respond to your inquiry concerning the extent and limits of the Agency's general authority over food and drug products containing nicotine. The Agency may assert jurisdiction over nicotine-containing food or drug products if those products meet the relevant definitions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). A more complete discussion follows.

Under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), "drugs" are defined as: (A) articles recognized in an official compendium, (B) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, (C) articles (other than food) intended to affect the structure or a function of the body, and (D) articles intended for use as a component of a drug. Under 201(f) of the FD&C Act, 21 U.S.C.321(f), "food" is defined as: (1) articles used for food or drink, (2) chewing gum, and (3) articles used for components of food.

The circumstances in which nicotine-containing products have satisfied these definitions are limited. Historically, FDA has not considered traditional tobacco-containing products, as customarily marketed, to be subject to regulation under the FD&C Act. Examples of these types of products are smoking tobacco, cigarettes, cigars, chewing tobacco, and snuff. On December 5, 1977, FDA denied a citizen petition that requested that it assert jurisdiction over traditionally-marketed forms of cigarettes as drugs. This denial was upheld in Action on Smoking and Health v. Harris, 655 F.2d 236 (D.C. Cir 1980).

FDA has in the past, however, regulated tobacco products as drugs when health claims were made by the manufacturers or vendors, such as representations that tobacco products were effective for the prevention or treatment of respiratory or other diseases or for weight reduction. For example, FDA brought an action against cigarettes that contained tartaric acid, a component that was represented to be effective for combatting obesity. The court held that these cigarettes were indeed a drug because of weight-reducing claims made in advertising and on the cigarette packaging. (See United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes 178 F. Supp. 847 (D.N.J. 1959).

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Another example of FDA regulatory action regarding nicotine-containing products is that on February 9, 1987, FDA sent a regulatory letter to the manufacturer of "Favor Smokeless Cigarettes" and "Favor Smoke-Free Cigarettes," which contained nicotine purportedly derived from tobacco, but no tobacco. These products were represented as a novel nicotine delivery system and a method of administering nicotine by inhalation of nicotine vapor. In these products, a fibrous plug impregnated with a nicotine solution was inserted within a small plastic tube resembling a conventional cigarette in appearance. The regulatory letter advised the firm that "Favor" is a nicotine delivery system intended to satisfy a nicotine dependence and to affect the structure and one or more functions of the body, and that because of its intended uses, "Favor" is a drug. FDA also advised that, in fact, "Favor" is a "new drug" within the meaning of section 201(p) of the FD&C Act because its composition is not generally recognized, among qualified experts, as safe and effective for use under the prescribed or recommended conditions as described in its labeling. The manufacturer had disagreed with our conclusion that "Favor" is a new drug but did suspend distribution and promised to inform the Agency in advance if it contemplated resumption of marketing.

As you know, FDA has also regulated "Nicorette" as a drug. It is clearly intended and labeled as a smoking deterrent to satisfy a nicotine dependence, following the cessation of smoking. "Nicorette" was originally developed and marketed in Europe, and in the early 1970's, clinical investigators in this country became interested in studying the product. They submitted to FDA investigational new drug applications in an effort to determine its safety and efficacy as a smoking deterrent. Soon after, Merrell Dow Pharmaceuticals, Inc., became interested in marketing "Nicorette" as well and submitted safety and efficacy data to the Agency. The NDA for "Nicorette" was approved by FDA on January 13, 1984.

Masterpiece Tobacs primarily consists of gum, tobacco, sweeteners and flavoring. It looks, tastes, and chews like chewing gum and because of the flavors and sweeteners in the gum, the saliva is likely to be swallowed as in gum chewing rather than expectorated. Further, it is unlike traditional smokeless tobacco products. Thus, we believe that Masterpiece Tobacs is a chewing gum and a food under the FD&C Act.

We also believe that this product is an adulterated food because it contains the ingredient tobacco, which is not generally recognized as safe (GRAS) for use in foods, and there is no regulation authorizing the use of tobacco in chewing gum. This product is, therefore, subject to legal action because it contains a food additive deemed unsafe within the meaning of section 409 of the FD&C Act and is, thus, considered to be adulterated within the meaning of section 402(a)(2)(C) of the FD&C Act. I have enclosed a copy of a letter to Mr. Stuart Pape that addresses the product Masterpiece Tabacs.

We are currently pursuing an investigation of IPCO Creamy Snuff to further evaluate its status with respect to the Federal Food, Drug and Cosmetic Act. In this regard, an assignment was sent to our Philadelphia District Office on July 31, 1987. Preliminary information indicates that the product may not be subject to the drug sections of the Act, but we are continuing our investigation.

I hope the preceding information has been helpful. If I can provide you with additional information, please don't hesitate to call me.

Sincerely yours,

Frank E. Young, M.D., Ph.D.
Commissioner of Food and Drugs

Enclosure